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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/620,794

07/15/2003

Jeff J. Staggs

1100

71977 7590 02/17/2010  
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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

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DELIVERY MODE

02/17/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,794	<b>Applicant(s)</b> STAGGS, JEFF J.	
	<b>Examiner</b> KEVIN WEDDINGTON	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 6 is/are allowed.
- 6) ☒ Claim(s) 1, 4 and 7-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

Claims 1-22 are presented for examination.

Applicant's amendment and response filed October 19, 2009 has been received and entered.

Claims 2 and 3 are considered to be cancelled since the applicant's amendment dated February 28, 2005 withdraws the claims before examination of the application.

Accordingly, the rejection made under 35 USC 112, first paragraph (Written Description) as set forth in the previous Office action dated June 10, 2009 at pages 5-7 as applied to claims 4 and 7 is hereby withdrawn because of applicant's remarks.

Accordingly, the rejection made under 35 USC 103(a) as being obvious over Gal, Zeitschrift fuer Lebensmittel-Untersuchung und-Forschung (1964), 124(5), pp. 33-6 or Chen et al., Chinese Journal of Microbiology and Immunology, Vol. 18, No. 3, pp. 190-195 (Aug, 1985), all of record, for reasons of record as set forth in the previous Office action dated June 10, 2009 at pages 9-10 as applied to claims 7-16 and 18-20 is hereby withdrawn because of applicant's remarks.

***Allowable Subject Matter***

Claims 5 and 6 are allowable.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an infectious disease caused by a drug-

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resistance strain of bacteria such as *Staphylococcus aureus* with pepper, does not reasonably provide enablement for treating other infectious diseases caused by other types of drug-resistant strains of bacteria such as *Streptococcus* or *Clostridium difficile* with pepper. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

Applicant's arguments regarding the In re Wands analysis are not required and are not persuasive since the applicant's instant specification only shows one example for the treatment of a drug-resistant strain of bacteria such as *Staph aureus* on page 15, lines 13-31. Again, there are no examples showing other drug-resistant strains of bacteria such as *Streptococcus* or *Clostridium difficile* were eradicated with pepper.

Would a practitioner of the art being of a M.D. administer a drug unknown or does not have experimental data showing the drug is effective against certain drug-resistant bacteria to a patient and a successful outcome.

The rejection made under 35 USC 112, first paragraph (Written Description) is adhered to.

Claim 1 is not allowed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rendered indefinite and vague because the applicant left out some important steps such as the active agent.

The remaining claims 8-20 are rendered indefinite to the extent that they incorporate the above terminology.

Claims 21 and 22 are again rendered indefinite because the claims refer back to being "an equivalent", however, the term "or an equivalent" was deleted by the applicant. Claims 21 and 22 do not have antecedent basis for being an equivalent.

Claims 7-22 are not allowed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is again rejected under 35 U.S.C. 102(b) as being anticipated by Gal, Zeitschrift fuer Lebensmittel-Untersuchung und-Forschung (1964), 124(5), pp. 33-6 or Chen et al., Chinese Journal of Microbiology and Immunology, Vol. 18, No. 3, pp. 190-195 (Aug, 1985), all of record, for reasons of record as set forth in the previous Office action dated June 10, 2009 at pages 8-9 as applied to claim 4.

Applicant's remarks regarding the Gal reference does not teach a phytoalexin derived from pepper to treat bacterial infections are not persuasive since the reference teaches a pepper such as paprika (also known as red pepper) have anti-bacterial properties. Since paprika (red pepper) has anti-bacterial properties, it does not matter what form it is in because the anti-bacterial properties are still there because a chemical composition and its properties are inseparable (See In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)).

The rejection made under 35 USC 102(b) is adhered to.

Claim 4 is not allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN WEDDINGTON  
Primary Examiner  
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